Registration Decision RD2011-11

Carbendazim

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Registration Decision for Carbendazim

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Carbendazim Technical and Polyphase 678 containing the technical grade active ingredients carbendazim and 3-iodo-2-propynyl N-butylcarbamate (iodocarb), as a material preservative.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-04, *Carbendazim*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Carbendazim and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-04. This decision is consistent with the proposed registration decision stated in PRD2011-04.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-04, *Carbendazim* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Carbendazim?

Carbendazim is currently registered in Canada as a fungicide to control Dutch elm disease (*Ophiostoma ulmi* and *Ophiostoma novo-ulmi*). Carbendazim is a broad spectrum fungicide with systemic activity that inhibits fungal mitotic microtubule formation, thus affecting the growth and division of spores.

Health Considerations

Can Approved Uses of Carbendazim Affect Human Health?

Potential exposure to carbendazim may occur during the treatment of materials or when handling treated materials. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. In general, the health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products are used according to label directions. The risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The end-use product, Polyphase 678, was of low acute toxicity in rats via the oral, dermal and inhalation routes, was minimally irritating to the eye and slightly irritating to the skin of rabbits, and was not a dermal sensitizer in guinea pigs.

Health effects in animals exposed to carbendazim included effects on the liver, kidney, testis and blood parameters. Carbendazim does not cause mutations in genetic material, but affects cell division, resulting in an alteration in the number of chromosomes in cells. Carbendazim produced tumours of the liver and ovaries in mice given daily doses over their life span. No effects on reproduction were observed in animal reproductive toxicity tests, but other studies have demonstrated that the reproductive system, including fertility, of male rodents is affected following exposure to carbendazim. When carbendazim was given to pregnant animals, serious effects on the developing fetus were observed at doses that were not toxic to the mother, indicating that the fetus is more sensitive to carbendazim than the adult animal. These effects included malformations of the head, spine, ribs and sternum as well as early death of the embryo. There is currently a lack of information regarding the potential for carbendazim to impair development of the nervous system in the young. Because of these observations, extra protective factors were applied in the risk assessment to further reduce the allowable level of human exposure to carbendazim.

Risks in Residential and Other Non-Occupational Environments

Estimated risks for non-occupational exposure are not of concern.

Homeowners handling consumer products containing Polyphase 678 and individuals contacting surfaces treated with products containing Polyphase 678 can be exposed to residues of carbendazim and 3-iodo-2-propynyl N-butylcarbamate (iodocarb) on the skin and through incidental oral (hand-to-mouth) exposure. Taking into consideration the expected exposure, risks to these individuals are not of concern.

Risks in Secondary Occupational Environments

Estimated occupational risks to secondary workers are not of concern.

Workers handling consumer products containing Polyphase 678 can come in direct contact with carbendazim and 3-iodo-2-propynyl N-butylcarbamate (iodocarb) residues on the skin. Taking into consideration the expected exposure, risks to these individuals are not of concern.

Occupational Risks From Handling Polyphase 678

Occupational risks are not of concern when Polyphase 678 is used according to the proposed label directions, which include protective measures.

Chemical handlers who mix and load Polyphase 678 can come in direct contact with carbendazim and 3-iodo-2-propynyl N-butylcarbamate (iodocarb) residues on the skin or by inhalation. Therefore, the label specifies that chemical handlers mixing and loading Polyphase 678 must wear full face protection with cartridge respirator and chemical resistant gloves, coveralls, cap and boots. The label also requires that a closed system be used when mixing and loading Polyphase 678. Taking into consideration these label statements, the amount of product handled and the expectation of the exposure period for chemical handlers, risks to these individuals are not a concern.

Environmental Considerations

What Happens When Carbendazim Is Introduced Into the Environment?

Carbendazim is persistent in soil and moderately persistent in water, but is not likely to leach to groundwater. Carbendazim has a low solubility in water and is not likely to volatilize. Carbendazim was found to be somewhat toxic to aquatic organisms but bioaccumulation is unlikely. As carbendazim is to be used as a material preservative for use in aqueous paints and stains, masonry coatings, adhesives, caulks and sealants, joint cements, and inks, exposure to non-target organisms in the environment is considered to be negligible if used according to the product label.

Value Considerations

What Is the Value of Polyphase 678?

Polyphase 678 is a broad spectrum fungicide for use as a dry-film and in-can material preservative.

Polyphase 678 contains two active ingredients; carbendazim and iodocarb. Together they provide a broad spectrum activity against fungal organisms that are known to create spoilage problems under industrial conditions, therefore increasing the service life of the materials in which the product will be added. Polyphase 678 provides effective protection against decay fungi as a dry-film preservative for paints, stains and adhesives. It will also provide fungal control as an in-can and a dry-film preservative in joint cements, sealants, caulks, grout, and inks.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the label of Polyphase 678 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Polyphase 678 on the skin or through inhalation of spray mists, chemical handlers mixing and loading Polyphase 678 must wear full face protection with cartridge respirator and chemical resistant gloves, coveralls, cap and boots. The label also requires that a closed system be used when mixing and loading Polyphase 678.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-04, *Carbendazim)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.inforserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*